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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/082,805 | 02/21/2002 | William E. Ortyn | BIOL0038 | 2051 |

7590 03/02/2006

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EXAMINER

GABEL, GAILENE

ART UNIT PAPER NUMBER

1641

DATE MAILED: 03/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/082,805 | Applicant(s) ORTYN ET AL. | |
| | Examiner Gailene R. Gabel | Art Unit 1641 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34,35 and 37-53 is/are pending in the application.
- 4a) Of the above claim(s) 52 and 53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34,35 and 37-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 34,35 and 37-53 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 28, 2005 has been entered.

Amendment Entry

2. Applicant's amendment and response, filed November 28, 2005, is acknowledged and has been entered. The specification has been amended. Claim 36 has been cancelled. Claims 34 and 37-53 have been amended. Claims 52 and 53 remain withdrawn from further consideration as being directed to a non-elected invention. Accordingly, claims 34, 35, and 37-53 are pending. Claims 34, 35, and 37-51 and are under examination.

Withdrawn Rejections

3. All rejections not reiterated herein, have been withdrawn.
4. The rejections of claim 36 are now moot in light of Applicant's cancellation of the claims.

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- 5. In light of Applicant's amendment, the rejection of claims 34, 35, 37-51 under 35 U.S.C. 102(e) as being anticipated by Dunlay et al. (US Patent 6,620,591) is hereby, withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 34, 35, and 37-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 34, step a) is confusing because it is unclear what structural or functional cooperative relationship exists between the "label" in the labeled probe and the "at least one optical signaling component". If the two elements are the same, then consistency in terminology usage is essential in obviating this rejection. Alternatively, if the two elements are distinct, then their structural relationship must be clearly defined to render this instant claim clear and definite. Same analogous comments and problems apply to claims 35 and 40.

Claim 34, step b) lacks clear antecedent basis in reciting, "a plurality of different optical signaling components become bound to said feature" because step a) recites that there is "at least one optical signaling component". It appears that for a plurality of different signaling components (labels) to become [physically] bound to a feature, there should be "more than one" rather than "at least one" optical signaling component.

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- Accordingly, it is unclear how at least one labeled probe having at least one optical signaling component can pluralize into different optical signaling components by virtue of just binding to a particular feature in the object.

Claim 42, step a) is confusing because it is unclear what structural or functional cooperative relationship exists between the “label” in the labeled probe and the “at least one optical signaling component”. If the two elements are the same, then consistency in terminology usage is essential in obviating this rejection. Alternatively, if the two elements are distinct, then their structural relationship must be clearly defined to render this instant claim clear and definite. Same analogous comments and problems apply to claims 43, 45, and 46.

Claim 42, step b) lacks clear antecedent basis in reciting, “a plurality of different optical signaling components become bound to said feature” because step a) recites that there is “at least one optical signaling component”. It appears that for a plurality of different signaling components (labels) to become [physically] bound to a feature, there should be “more than one” rather than “at least one” optical signaling component. Accordingly, it is unclear how at least one labeled probe having at least one optical signaling component can pluralize into different optical signaling components by virtue of just binding to a particular feature in the object.

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- The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 34, 35, and 37-51 are rejected under 35 U.S.C. 102(e) as being anticipated by Garini et al. (US 6,066,459).

Garini et al. disclose a method for detecting a feature or a cellular component, in an object or a cell, using an imaging system. Garini et al. teach providing at least one probe having a fluorescent label or dye, i.e. optical signaling component, conjugated thereto. Garini et al. teach using different fluorophores for each probe or a plurality or combination of different fluorophores for every probe (different optical signaling components). See Abstract, column 1, lines 24-48, and column 13, lines 13-30. The probe selectively binds to at least a portion of the cellular component, i.e. chromosome in the cell nucleus, within the cell. The labeled probe is then contacted with the cell so as to bind the labeled probe to the selected cellular component. Fluorescence excited by white or coherent light is detected in few narrow spectral bands, and collected from the cell along a collection path, wherein the light collected corresponds to each of the plurality of different fluorescent dye combinations or different optical signaling components. The collected light is focused to produce an image of the cell nucleus, which is viewed through a fluorescence microscope that is optically connected to an

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imaging system (spectrometer). Locations of the labeled probe bound to the selected portion of the cellular components that are imaged are optically and spectrally discriminated. Therein, multiple spectra each representing a different probe, are simultaneously collected and measured. The imaging system is capable of obtaining a spectrum of each pixel of the cell nucleus (see column 29, lines 27-46 and column 34, line 29 to column 35, line 21). The signal is then analyzed to determine if a spectral component from the combination of fluorophore dyes that are conjugated to the labeled probe that bound, are present in the image, to hence establish that the cellular component is integral part of the cell. The method is highly sensitive both in spatial and spectral resolutions; hence is capable of simultaneous detection of combinations of fluorophores. See especially column 6, line 58 to column 7, line 46 and column 8, lines 5-13.

Response to Arguments

8. Applicant's arguments with respect to claims 34, 35, and 37-51 have been considered but are moot in view of the new grounds of rejection.

9. No claims are allowed.

Remarks

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- 10. Prior art made of record are not relied upon but considered pertinent to the applicants' disclosure:

Zhang et al. (US Patent 5,786,219) disclose microspheres having fluorescent zones for use as labels in combinatorial analysis (see Abstract and columns 3, 4, and 15).

- 11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gailene R. Gabel

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- Patent Examiner
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February 22, 2006

A handwritten signature in black ink, appearing to be "J. H. H.", is written over the text "February 22, 2006".